

Plain Language Statement

Department of Physiotherapy
School of Health Sciences
Faculty of Medicine, Dentistry and Health Sciences



Project:

Development of a “core set” of outcome measures for spasticity trials and clinical practice

Phase 2 and Phase 4: Modified Delphi Survey

Groups 1-3: Academic experts, Clinical experts and Industry representatives

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Introduction

Thank you for your interest in participating in this research project. The following few pages will provide you with further information about the project, so that you can decide if you would like to take part in this research. Please take the time to read this information carefully. You may ask questions about anything you don't understand or want to know more about. Your participation is voluntary. If you don't wish to take part, you don't have to. If you begin participating, you can also stop at any time. You will be asked to check the following boxes electronically, prior to commencing the survey:

- I confirm that I have read the plain language statement dated 21/03/2025 (version 3) for the current study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily ☐
- I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected ☐
- I understand that all data will be confidential and securely stored. I understand that if I withdraw from the study my processed data up to the point of withdrawal may have already been used in the analysis. I will be able to request the withdrawal of any unprocessed data. ☐

- I agree to take part in the study ☐

What is this research about?

Spasticity is common in people with neurological conditions such as stroke, brain injury and multiple sclerosis. Spasticity can cause pain, reduced range of motion or compromised skin integrity and has been shown to negatively impact walking, arm use, personal-care, and quality of life. While there is a lot of research in the field of spasticity assessment and management, this research is hampered by a lack of consistency in the way that spasticity, and the associated problems that it may cause, are measured. This makes it difficult for both researchers and clinicians to compare results between studies (i.e., complete a meta-analysis) and establish the most effective treatment options for people with spasticity.

To address this problem, other areas of healthcare such as stroke have developed a 'core set' of outcome measures (i.e. minimum accepted outcome measures) that trials need to measure and report when conducting research in their designated field. This has led to better reporting in clinical trials and greater capacity to compare the results of clinical trials. This project, which will be conducted internationally, aims to develop a core set of outcome measures for spasticity, in order to enhance spasticity related research and optimise clinical care and patient outcomes. It will enable greater clarity, consistency, evaluation and comparison of spasticity trials.

The first stage of this project involved identifying relevant assessment domains via:

- Internationally published spasticity guidelines; and
- A small number of interviews conducted with individuals with spasticity and/or their carer.

You have been invited to participate in the second and third stage of this study because you are either an academic or clinical expert in the field of spasticity or an international pharmacological/industry representative.

What will I be asked to do?

Should you agree to participate, you will be asked to complete two separate Modified Delphi Processes. Each will involve 2-3 rounds of an online survey, that will be sent to your email using an online platform called REDCap. It is anticipated that each survey will take approximately 20-30 minutes to complete, with each round taking less time. The surveys will be sent approximately 4-6 weeks apart, with a longer break between the first and second Modified Delphi process (outlined below). A reminder will be sent two weeks after each survey has been sent.

Data collected within the survey will include:

i) Demographic data (initial survey only):

- Age (in 5-year bands);

- Gender;
- Country;
- Role (e.g. clinician, researcher, pharmaceutical representative, person with lived experience or their carer);
- Discipline (e.g. rehabilitation physician, physiotherapist, occupational therapist, etc);
- Years of experience working in spasticity (in 5-year bands).

ii) Modified Delphi 1 - Rating of assessment domains:

You will be presented with each of the domains identified in the first stage of the project. These domains may include things such as pain, joint range of motion, walking and quality of life. In the first round of the survey, you will be asked to rate how important you believe it is that each domain is assessed as a part of spasticity management. This will be done on a nine-point scale ranging from critically important to limited importance. Free text boxes will be available to suggest any further domains, or add any relevant comments. The research team will then apply pre-established consensus criteria to all of these domains. In round 2, you will be presented with a summary of results any relevant comments or feedback regarding each domain. You will be asked to re-score domains where consensus was not reached, as well as to score any new domains that were identified in the first survey. Where there is no clear consensus regarding whether a domain should be included or excluded, a third survey will be sent to you with similar data provided to that in the second round.

If consensus is still not reached after the third round, you may be invited to a final consensus meeting, which will be held via Zoom with participants across each of the stakeholder groups (clinicians, academics, industry representatives and patients/carers). The consensus meeting will involve a presentation of the results and commentary regarding the domains under question and each participant will have a final opportunity to vote on these domains. This consensus meeting will be audio recorded and transcribed into text using the Zoom audio transcription function, to enable the researchers to re-listen to the meeting, ensuring that no important content is omitted. This will mark the final stage of this aspect of the study.

Once the domains to be included in the core outcome set have been confirmed, the research team will then identify the relevant outcome measures for each of the domains included, as well as the psychometric properties of each of these measures. The quality of these measures will be evaluated using pre-determined criteria and the outcome measurements that meet these criteria will then be presented in the second Modified Delphi process (outlined below). Individuals with spasticity and their carers won't be involved in the second Modified Delphi Process.

iii) Modified Delphi 2 – Selection of outcome measures to include in the core set:

You will then be requested to undertake a similar process to the first Modified Delphi in order to finalise the exact assessment measures to be included in the core outcome set. As outlined above, this will involve 2-3 survey rounds and an invitation to take part in a

consensus meeting to establish final agreement regarding the measures to be included in the core set.

What are the possible benefits?

The main benefit resulting from this project is the opportunity to improve how spasticity research trials are conducted and reported, enabling greater comparison between trials and ultimately an improved outcome for individuals with spasticity following neurological injury.

What are the possible risks?

This project poses negligible risk to participants. The only risk is the minimal time burden associated with the survey rounds. However, you will be entitled to take breaks throughout the survey, exit and return as needed. Additionally, you will be given approximately three weeks to complete each survey round.

Do I have to take part?

No, participation is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you decide to withdraw from the project, please notify a member of the research team as soon as possible. If you decide to withdraw from this research project, the researchers will not collect additional information from you. Any information already collected from you will still be used in this project, unless you request otherwise.

Will I hear about the results of this project?

Following the completion of these surveys you will receive an email summary of the results outlining the assessment domains to be included in the core outcome set, as well as a copy of the final core outcome set.

What will happen to information about me?

By ticking the consent boxes prior to commencing the survey, you consent to the research team collecting and using personal information about you for the purposes of this research project only. Any information obtained in connection with this research project that can identify you will remain confidential and will only be re-identifiable to the researchers named on this application. Your information will be stored in a statistical software package, extracted from REDCap, that will remain password protected. No attempt will be made to identify your individual responses when analysing or presenting the data. Your data will be unidentifiable when referred to in any publications or presentations.

All data generated will be collected, managed, and stored following the protocols outlined in the University of Melbourne's "Management of Research Data and Records Policy". The data will be kept on a university system (OneDrive) accessed by secure password-protected computers, which will only be accessed by the researchers.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified.

All data will be held for 5 years after the last report is published. The data will be stored digitally by The University of Melbourne on password protected cloud software. After this time, the data will be destroyed to ensure confidentiality is maintained.

Who is funding this project?

No member of the research team will receive a personal financial benefit from your involvement in this research project.

Where can I get further information?

If you would like more information about the project, please contact the principal researcher:

Name: Professor Gavin Williams

Position: Project Supervisor

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Who can I contact if I have any concerns about the project?

This project has human research ethics approval from The University of Melbourne [Project ID 31748]. If you have any concerns or complaints about the conduct of this research project, which you do not wish to discuss with the research team, you should contact the Research Integrity Administrator, Office of Research Ethics and Integrity, University of Melbourne, VIC 3010. Tel: +61 3 8344 1376 or Email: research-integrity@unimelb.edu.au. All complaints will be treated confidentially. In any correspondence, please provide the name of the research team and/or the name or ethics ID number of the research project.